K081485

Section 5: 510(k) Summary

SEP 18 2008

510(k) Summary

Applicant:
Somnomedics GmbH
Am Sonnenstuhl 63
Randersacker, Germany D-97236
Phone: +49 931 35 90 94 0
Facsimile: +49 931 35 90 94 49

US Contact:
M Squared Associates, Inc.
Cherita James
901 King Street, Suite 200
Alexandria, Virginia 22314
Phone: 703-562-9800 ext. 257
Facsimile: 703-562-9797
E-mail: CJames@msquaredassociates.com

Date submitted: May 28, 2008

Proprietary Name: Somnomedics SOMNOwatch
Common Name: Activity Recording Device
Classification Status: Class II per regulations §882.1400, §868.2375
Product Codes: GWQ, MNR
Establishment Registration Number: Applied for, not yet assigned
Manufacturing/ Distribution Address:
Somnomedics GmbH
Am Sonnenstuhl 63
Randersacker, Germany D-97236

Predicate Devices:
- ActiTrac (K992410); Individual Monitoring Systems (IM-systems), Inc.
- SOMNOscreen (K060708), SOMNOmedics GmbH

Device Description

The SOMNOwatch is a small, portable physiological signal recording system intended to be used to record, display, monitor, print and store biophysical events to aid in the diagnosis of sleep disorders. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home.

This device is NOT designed to be used in a Life Support situation.

Indication for Use

The SOMNOwatch is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having movement-correlated sleep disturbances.

Intended Use

The SOMNOwatch is a small, typically wrist-worn activity monitor. The device is intended to be used to analyze circadian rhythms, automatically collect and score data for sleep parameters. These parameters, representing the number and intensity of limb movements, are directly associated to movement-correlated sleep disturbances. The unit can also be used to assess activity in any instance where quantifiable analysis of physical motion is desired. For PLM-detection two identical SOMNOwatches may be affixed to the patients legs, one to each leg.

Technical Specifications of the SOMNOwatch

CHANNELS	6 Internal Channels: (3 Activity Sensors for X-Y-Z Axis, Body Position, Ambient Light, Patient Marker)
DATA PROCESSING	12 Bit ADC Different Sampling Rates Adjustable (1/120s - 128/s) Different Storage Rates Adjustable (1/120s - 128/s)

Summary of Technological Characteristics

The SOMNOwatch utilizes a motion sensor, an *accelerometer* ,to monitor the occurrence and degree of motion. This type of sensor provides an analog signal where the amplitude and speed of motion produces a signal whose magnitude and duration depend on the amount of motion. The activity signals are amplified and digitized by on-board circuits within the device. This information is stored in the internal memory of the device. The system provides

up to 6 channels for data acquisition; 3 Acceleration for X-Y-Z Axis, Ambient Light, Patient Marker and Body Position.

Information is stored on an internal 8 MB Flash and can be transferred to a PC via a USB docking station. The DOMINOlight software retrieves the data from the SOMNOwatch, displays the data, and can store data for future reference and comparison. DOMINOlight also allows automatic analysis of all signals including the body position.

Summary of Nonclinical Testing

Performance testing was conducted to confirm compliance to device specifications. All functions were verified to operate as designed. Testing to the international standards for electrical safety and electromagnetic compatibility were performed. The SOMNOwatch was found to be compliant with the requirements of these standards for it's intended use.

Clinical Testing

Comparison studies of the SOMNOwatch and the predicate devices found the subject device can be expected to provide safety and effectiveness outcomes substantially equivalent to the predicates.

Conclusion

SOMNOmedics SOMNOwatch has the same principles of operation and similar technological characteristics as the Actitrac. While the principle of operation and method of data collection differ from the SOMNOscreen, the differences do not present new issues of safety or effectiveness as demonstrated in the clinical comparison.

Based on performance testing, the SOMNOmedics SOMNOwatch is substantially equivalent to devices already on the market and presents no new concerns of safety and effectiveness. Additionally, the device has similar indications to the predicate devices and the labeling of the device is consistent both with FDA's guidance as well as current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Somnomedics GmbH
C/O Ms. Cherita James
Regulatory Consultant
M Squared Associates, Incorporated
901 King Street, Suite 200
Alexandria, Virginia 22314

Re: K081485
Trade/Device Name: SOMNOwatch
Regulation Number: 21 CFR 868.2376
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: May 28, 2008
Received: May 28, 2008

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): _____

Device Name: SOMNOwatch

Indications For Use: The SOMNOwatch is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having movement-correlated sleep disturbances.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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